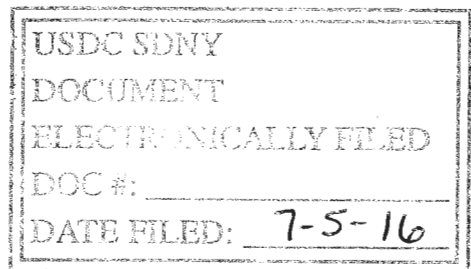


UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK



-----X
KOWA COMPANY, LTD., et al.,

Plaintiffs,

-against-

SAWAI USA, INC. and SAWAI
PHARMACEUTICAL CO., LTD.,

Defendants.
-----X

14 Civ. 5575 (PAC)

OPINION & ORDER

HONORABLE PAUL A. CROTTY, United States District Judge:

Defendants Sawai USA, Inc. and Sawai Pharmaceutical Co, Ltd. (collectively “Sawai”) move for leave to amend their answer and counterclaims to add allegations that Plaintiff Kowa Company, Ltd. (“Kowa”) engaged in inequitable conduct in obtaining a patent at issue in this suit and, consequently, the patent is invalid and unenforceable. The motion (which none of Sawai’s co-defendants join) is denied; it was made long after the agreed-upon deadline for amendments, seeks to add voluminous allegations, would require reopening fact discovery, and would quite certainly delay the resolution of this complex patent case.

BACKGROUND

Kowa, manufacturer of the cholesterol-lowering drug Livalo, brought this action on July 23, 2014, alleging that Sawai, in seeking FDA approval to market and sell generic versions of Livalo, are infringing Kowa’s U.S. Patents No. 5,856,336 (“the ‘336 Patent”), 6,465,477 (“the ‘477 Patent”), and 8,557,993 (“the ‘993 Patent”). Kowa also sued six other sets of generic drug manufacturer defendants in related actions. On September 12, 2014, Sawai USA answered the

complaint and pleaded counterclaims. Dkt. 16. On March 19, 2015, Sawai Pharmaceutical answered and counterclaimed, having previously made and then withdrawn a motion to dismiss for lack of personal jurisdiction. Dkt. 67, 68, 70.

On October 17, 2014, the Court approved the parties' proposed Civil Case Management Plan and Scheduling Order, which applies to all seven actions and provides that amendments to the pleadings were to be filed by March 2, 2015, and fact discovery would be completed by October 5, 2015. Dkt. 39 ¶¶ 3, 5. The Court subsequently approved numerous extensions to the Scheduling Order. On February 29, 2016, the Court approved extending the close of fact discovery to April 6, 2016; this was the thirteenth modification to the Scheduling Order and the third extension of the close of fact discovery. Dkt. 111 at 4.

On February 17 and 18, 2016, Sawai deposed Dr. Masaki Kitahara, one of the inventors whose declarations Kowa used to secure the '336 Patent and other related prior patents. On April 6, 2016, fact discovery ended. On April 13, Sawai filed a pre-motion letter seeking leave to amend its defenses and counterclaims to add allegations of inequitable conduct, premised in part on Dr. Kitahara's testimony. Dkt. 113. On April 27, the Court granted Sawai leave to so move and set a briefing schedule. Dkt. 116. While briefing was ongoing, the Court set a trial date of January 17, 2017, with approval from Kowa, Sawai, and the six other sets of defendants. Dkt. 122. To meet that trial date, the parties have agreed to exchange all expert reports by August 19, complete expert discovery by October 14, file dispositive motions by November 11, and file final pretrial submissions by November 18. Dkt. 124.

All documents that Sawai used at Dr. Kitahara's deposition are either publicly available or were produced by April 30, 2015. Pl. Opp. Mem. at 1. At the deposition, Sawai showed Dr. Kitahara a copy of the '336 Patent, which the Patent and Trademark Office issued on January 5,

1999. Ex. C at 83.¹ He confirmed that he was listed on the patent as an inventor and recalled that his contribution was “[m]easurements of the activity of compounds.” *Id.* at 83-84. Beyond that, he could remember almost nothing more about his work on the compounds or the methods described in the patent. *Id.* at 84-99.

Sawai also showed Dr. Kitahara three of his signed declarations. The first declaration, dated April 9, 1991, was submitted by Kowa during the prosecution of a parent patent to the ‘336 Patent. Ex. E. In that declaration, Dr. Kitahara states:

[T]he compounds of this invention exhibit unobvious superiority . . . when compared with referenced compounds of the prior art . . . This enhanced activity could not be predicted on the basis of structure, or information available to those of ordinary skill in the art as of the effective filing date of this application.

Id. at 3-4. The second and third declarations, dated June 1, 1992 and July 6, 1992, were submitted by Kowa during an interference proceeding to determine the priority (and thus enforceability) of a previously-issued grandparent patent to the ‘336 Patent. Ex. G, H. The declarations similarly describe the unexpected and “unobvious” superiority of certain compounds. Ex. G at 4; Ex. H at 2. And Dr. Kitahara similarly affirms that the superior activity could not be predicted by an individual “having the approximate level [of skill] of a graduate chemist with several years of experience in the field” on the basis of structural comparison alone. Ex. G at 4.

When shown these three documents, Dr. Kitahara could remember almost nothing about them; indeed it seems he barely recognized them. To provide a few examples, Dr. Kitahara did not know why the compounds described were superior to other referenced compounds or had enhanced activity; why these findings were “unobvious”; or why they could not be predicted by

¹ All cited exhibits are in the Declaration of Azy S. Kokabi, submitted by Sawai under seal on May 12, 2016.

a person with ordinary skill in the art or with graduate-chemistry-level skill. *See, e.g.*, Ex. D at 262-71. He also repeatedly testified that he did not write various portions of the declarations. *Id.* at 264-68.

Sawai's motion also relies on a fourth Kitahara declaration, which they did not show Dr. Kitahara or inquire about at his deposition. This declaration, dated May 25, 1992, was submitted by Kowa during the prosecution of the '336 Patent itself. Ex. F. It similarly describes a compound that exhibits "unobvious superiority," which "could not be predicted on the basis of structure, or information available to those of ordinary skill in the art as of the effective filing date of this application." *Id.* at 3.

SAWAI'S MOTION

Sawai seeks leave to amend its pleadings to allege that Kowa engaged in inequitable conduct by submitting to the patent examiners the four Kitahara declarations, which contain false statements because Dr. Kitahara signed them (and affirmed their accuracy) without personal knowledge of the statements contained therein. Ex. A ¶ 49. Sawai alleges that those falsehoods are "highly material" because but for the examiners accepting the declarations as true, the grandparent patent, parent patent, and '336 Patent would not have issued. *Id.* Sawai further alleges "[o]n information and belief, Dr. Kitahara signed each of his four declarations with specific intent to deceive the patent Examiners." *Id.* Those allegations, Sawai contends, are sufficient if proven to render the '336 Patent invalid and unenforceable.

In addition, Sawai seeks leave to allege inequitable conduct on grounds that Dr. Kitahara failed to disclose to the examiners (i) the margin of error associated with some of his submitted data; (ii) that the test results reported were not conducted in a side-by-side test; and (iii) that he cherry-picked the submitted data. Def. Mem. at 10. Again, Sawai alleges that the examiners

would not have issued the patents but for these omissions and, on information and belief, Dr. Kitahara omitted this information with specific intent to deceive the patent examiners. *See, e.g.*, Ex. A ¶¶ 93, 94, 104-06. None of the other six sets of defendants join in Sawai's motion.

Sawai submits two proposed amended answer and counterclaims, one for Sawai Pharmaceutical and one for Sawai USA. The initial Sawai Pharmaceutical pleading is 23 pages with 46 numbered paragraphs; the proposed amended pleading is 72 pages with 202 numbered paragraphs. *Compare* Dkt. 70 with Ex. A. The initial Sawai USA pleading is 20 pages with 47 numbered paragraphs; the proposed amended pleading is 69 pages with 202 numbered paragraphs. *Compare* Dkt. 16 with Ex. B.

DISCUSSION

I. Legal Standard

Rule 15 of the Federal Rules of Civil Procedure provides that leave to amend the pleadings should be “freely give[n] . . . when justice so requires.” “Reasons for a proper denial of leave to amend include undue delay, bad faith, futility of amendment, and perhaps most important, the resulting prejudice to the opposing party.” *AEP Energy Serv. Gas Holding Co. v. Bank of Am., N.A.*, 626 F.3d 699, 725 (2d Cir. 2010). “Amendment may be prejudicial when, among other things, it would require the opponent to expend significant additional resources to conduct discovery and prepare for trial or significantly delay the resolution of the dispute.” *Id.* at 725-26. Further, Fed. R. Civ. P. 16 requires that where a party seeks to amend a pleading after the prescribed deadline in a scheduling order, it must show “good cause” for the belated amendment. *Pres. Church of Sudan v. Talisman Energy, Inc.*, 582 F.3d 244, 267 (2d Cir. 2009).

II. Analysis

The Court denies leave to amend because permitting amendment would be prejudicial

and unduly delay resolution of the matter. Sawai moved to amend 21 months after Kowa commenced the action, a year after the amendment deadline, and after the close of protracted and repeatedly extended fact discovery. And the amendment is not a modest proposal. First, there is its prolixity. Sawai seeks to triple the number of pages in its pleadings and quadruple the number of paragraphs to which Kowa must answer and ultimately defend against.

Then there is the claim itself. As the *en banc* Federal Circuit recently explained, “inequitable conduct is the atomic bomb of patent law” because “[u]nlike validity defenses, which are claim specific, . . . inequitable conduct regarding any single claim renders the entire patent unenforceable.” *Therasense, Inc. v. Becton, Dickinson and Co.*, 649 F.3d 1276, 1288 (Fed. Cir. 2011) (*en banc*). Further, and as Sawai alleges applies here, “the taint of a finding of inequitable conduct can spread from a single patent to render unenforceable other related patents and applications in the same technology family.” *Id.* And on a macro level, the *Therasense* court observed that “[i]nequitable conduct has been overplayed, is appearing in nearly every patent suit, and is cluttering up the patent system”; “[t]he habit of charging inequitable conduct in almost every major patent case has become an absolute plague.”² *Id.*

Given the breadth and gravity of Sawai’s allegations, as well as the fact that they are premised on decades-old conduct, Kowa would be entitled to additional fact and expert discovery to defend against the new claims. Kowa may seek to reopen Dr. Kitahara’s deposition

² To address these concerns, the *Therasense* court “tighten[ed]” the standards of proof for intent and materiality. *Id.* at 1290. The Court held that the party raising the defense must prove by clear and convincing evidence that “the specific intent to deceive [is] the single most reasonable inference able to be drawn from the evidence”; accordingly, “when there are multiple reasonable inferences that may be drawn, intent to deceive cannot be found.” *Id.* at 1291 (internal quotation marks omitted). Further, absent “affirmative egregious misconduct,” the party invoking the defense must prove “but-for materiality”—that the patent office would not have allowed the claim if it had been aware of the undisclosed or erroneous information. *Id.* at 1291-92. And even if all the elements are met, the Court “must weigh the equities to determine whether the applicant’s conduct before the [patent examiners] render[s] the entire patent unenforceable.” *Id.* at 1287.

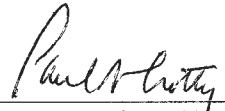
and, as they indicate in their brief, they may be into entitled to discovery into Sawai's conduct. Pl. Opp. Mem. at 7. Accordingly, permitting amendment would cause Kowa to incur significant additional expenses and cause further delays in this already drawn-out litigation, to the detriment of Kowa, the Court, and perhaps the six other sets of defendants that do not join Sawai's motion and have already agreed to a date for consolidated trial. Such prejudice warrants denial of the motion.³

CONCLUSION

The Court DENIES Sawai's motion to amend. The Clerk is directed to terminate all open motions.

Dated: New York, New York
July 5, 2016

SO ORDERED



PAUL A. CROTTY
United States District Judge

³ In addition, Sawai unduly delayed in seeking to add the allegations regarding failure to disclose margins of error, side-by-side comparisons, and cherry-picked data. Sawai had all the information they rely on in making those allegations by April 30, 2015. Sawai's delay of nearly a year in seeking to add those claims is improper and further supports denial of the motion.